

Remarks

Amendments to the Claims

The preambles of independent claims 1 and 7 have been amended to recite a method for identifying a compound “potentially useful for” treating a cardiovascular disorder or a thrombotic disorder. A corresponding amendment is made to step (b) of each claim. The specification supports these amendments in paragraph [000225]: “Compounds identified via assays such as those described herein may be useful, for example, for ameliorating cardiovascular disease, *e.g.*, atherosclerosis and/or thrombosis.” The amendments add no new matter.

The Rejection of Claims 1-11 Under 35 U.S.C. § 101

Claims 1-11 stand rejected under 35 U.S.C. § 101 as lacking patentable utility. Applicant respectfully traverses the rejection.

The specification needs to make only one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112. *Raytheon v. Roper*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) (“When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.”). The specification makes such an assertion. On page 13, the specification teaches that modulators of polypeptide 6169 are useful in treating disorders associated with cardiovascular disease, including the elected specifics of atherosclerosis. Unless there is reason to doubt the asserted utility, Applicants are entitled to a presumption that the asserted utility is sufficient to satisfy 35 U.S.C. § 101:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391 183 U.S.P.Q. (BNA) 288, 297 (C.C.P.A. 1974).

To overcome the presumption that Applicants' asserted utility is true, the U.S. Patent and Trademark Office must establish by a preponderance of the evidence that it is more likely than not that one of ordinary skill in the art would question the truth of the statement of utility. M.P.E.P. § 2107.2(III)(A). The Office Action has not provided such evidence. The Office Action merely asserts that the specification's asserted utility is not credible. Office Action at page 3.

Applicants do not have to provide evidence sufficient to establish that the specification's asserted utility for the disclosed protein is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 U.S.P.Q. (BNA) 351, 354 (C.C.P.A. 1965). Patentability of the claimed invention must be assessed "on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d (BNA) 1443, 1444 (Fed. Cir. 1992). A preponderance of the evidence exists when the evidence suggests that it is more likely than not that the assertion in question is true. *Herman v. Huddleston*, 459 U.S. 375, 390 (1983).

It is the U.S. Patent and Trademark Office's burden to establish that the evidence of record, considered as a whole, leads a person of ordinary skill in the art to doubt that the asserted utility is true. M.P.E.P. § 2164.07(I)(C). The Office Action does not meet this burden. The Office Action has not provided any evidence which call the specification's asserted utility into

doubt. Thus, the U.S. Patent and Trademark Office has not made a *prima facie* case that claims 1-11 lack utility.

Applicant respectfully requests withdrawal of the rejection.

The Rejection of Claims 1-11 Under 35 U.S.C. § 112, first paragraph

Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. Applicant respectfully traverses the rejection. This rejection is based on the assertion that these claims lack patentable utility. As explained above, the U.S. Patent and Trademark Office has not met its burden of establishing a *prima facie* case that the claims lack patentable utility. The Office Action asserts no other reason why the claims are not enabled.

Applicant respectfully requests withdrawal of the rejection.

Rejection of Claims 1-11 Under 35 U.S.C. § 112 ¶ 2

Claims 1-11 stand rejected as indefinite under 35 U.S.C. § 112 ¶ 2. Applicant respectfully traverses the rejection.

The Office Action asserts that the phrase “to thereby identify a compound which binds to the polypeptide” in step (b) of independent claims 1 and 7 is indefinite and the claim preambles do not correspond to the method outcomes. To advance prosecution, claims 1 and 7 have been amended to delete the phrase “to thereby identify” and to make the preambles correspond to the method outcomes.

Please withdraw the rejection.

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Respectfully submitted,

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